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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/202,035	12/17/1998	JEFFREY JOHN GORMAN	415852000100	2384

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GLADYS H. MONROY
MORRISON & FOERSTER
755 PAGE MILL ROAD
PALO ALTO, CA 94304-1018

EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	26

DATE MAILED: 03/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/202,035	Applicant(s) GORMAN, JEFFREY JOHN	
	Examiner Bao Qun Li	Art Unit 1648	

-- The MAILING DATE of this c mmunication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13,22,24,26 and 34-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13,22,24,26 and 34-42 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 25 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence letter* .

Notice to Comply	Application N .	Applicant(s)	
	Examiner	Art Unit	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Please provide the SEQ ID NO for the amino acid sequences cited in the claims.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

DETAILED ACTION

Claims 1-13, 16-18, 21-42 are pending.

Sequence requirements

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive. In the instant case, the sequences cited in the claims must be labeled with sequence identification number (SEQ ID NO).

Response to Amendment

This is response to the amendment C, paper No. 24, filed 01/02, 2002. Claims 14-15 and 19-20 are canceled. Claims 1-4, 6-13, 22, 24 and 26 are amended. Claims 34-42 are added. Claims 1-13, 22, 24, 26 and 34-42 in the scope of the SEQ ID NO: 1 are considered by the examiner.

Please note any ground of rejection that has not been repeated is removed.

The text of those sections of Title 35, U.S. code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-13, 22, 24 and 25 are still rejected under 35 USC § 112, second paragraph, on the similar grounds as previously stated in the office action mailed 06/20/01.

Claims 1, 5, and 6 are still vague and indefinite although Applicant amends the claims as " consisting essential of" instead of " having" because the citation of " consisting essential of" is still an open language, which fails to define which amino acid is essential amino acid that should be contained in the sequence and which other amino acid is not essential that is not necessarily contained in the sequence. If Applicants wish to claim a particular peptide in the claims, please amend the claims to a precise sequence that is intended. Therefore, the rejection is maintained and made Final.

Claim 2 is still vague and indefinite despite that Applicants argument. Although the "mutant" and "variant " are understood words in the art, they can not be defined in the claim which mutant and variant thereof are intended in the said claim. The rejection is therefore maintained and made Final.

Claim Rejections - 35 USC § 112

Claims 1-13, 22, 24, 26 are still rejected under 35 USC § 112, first paragraph, on the similar grounds as previously stated in the office action mailed 06/20/01.

Applicant argue that the rejection is only directed to the claims 22, 24 and 26 because only those claims are directed to the method of prevention. This argument is fully considered; however, it is not found persuasive. Because the claims 22, 24 and 26 were dependent on any of the claims 1 through 7 and cited to use any of the produce in claims 1 through 7 to prevent or immunize the mammal for free of the Pneumovirus infection. The ennoblement rejection is based on that the specification does not teach any of the product cited in the claims 1 through 7 is able to induce a protective immunity against Pneumovirus infection in vivo. Therefore, all of the claims 1-13, 22, 24 and 26 are rejected on the enablment issue.

In attempting to overcome the rejection, Applicant amends the claims 22, 24 and 26. However, the amendment render the even more broad scope for any or all peptide of peptidominetic compound or structural fragment thereof. This does not deem the claims in the condition for enablement because there is no any peptide disclosed in the specification is able to

induce a protective immunity against Pneumovirus infection. Therefore, the rejection is maintained and made Final.

Claim Rejections - 35 USC § 102

The claims 1-6, 8, 10, 22 and 24 are still rejected under 35 USC § 112 (e) over the Alkerlind-Stopner et al. (J. Virol. 1990, Vol. 64, pp. 543-5148) for the same ground as stated in the previous Office Action.

Applicant argue that Alkerlind-Stopner et al. merely shows that the cystein-containg region of the RSV G peptide. Applicant's argument is fully considered; however, it is not found persuasive because the claimed sequence disclosed by the Alkerlind-Stopner et al. et al. is within the frame of the claimed peptide of the instant Application and shows 100% homology to the claimed peptide SEQ ID NO: 1. Although Alkerlind-Stopner et al. et al. did not explicitly claim that the specific disulfide binding patter within the highly conserved, cystein-rich region of the peptide. Since the amino acid sequence is 100% homology to each other, the highly –conserved, cystein-rich region is inherently existed. Therefore, the rejection is maintained and made Final.

Claim Rejections - 35 USC § 103

The claims 1-13, 22 and 24 are still rejected under 35 USC § 112 (e) over the Alkerlind-Stopner et al. (J. Virol. 1990, Vol. 64, pp. 543-5148) and Guichard (PNAS 1994, Vol. 91, pp. 9765-9769) for the similar ground as stated in the previous Office Action.

The same notion as discussed above, Applicant argument is not persuasive in regarding that the disulfide bonding patter required by the claims of the present invention is merely discussed because the disulfide bound among the already existed cystein residue is inherent characteristic of the RSV G peptide disclosed in Alkerlind-Stopner et al.' reference (The Langedijk et al. reference is not considered because its late 102(e) date; however, Alkerlind-Stopner et al.' reference is still obvious to the claimed invention because it has similar disclosure of Langedijk et al. reference).

Applicant further argues that Guichard merely discloses retro-inverso-peptidominetic analogues of Nature L peptide. The combination of the references therefore, would not allow one to arrive at the present invention. Applicant's argument is fully considered; however, it is not found persuasive. Because Guichard et al.' reference does teach the method for making the

retroverso peptide or retroverso-D peptide. They concluded that the retro-inverso-peptide IRGERA mimicked the structure and antigenic activity of the nature L-peptide but not of the D—and retro-peptides, whereas the retro-peptide mimicked the D-peptide but not the L-and retroverso-peptides. The use of retro-inverso-peptide to replaces nature L-peptides is likely to fine many applications in immnodiagnosis and as potential synthetic vaccine (See Abstract). The use of the same method of Guichard for modifying another peptide with already known sequence is, therefore, so obvious for an ordinary skill in the art with highly predicted success. Hence, it is concluded that the rejection is maintained and made Final.

New Ground Rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13, 22, 24, 26 and 34-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 6 are vague and indefinite in that the metes and bonds of " a structural homologue thereof" are not defined. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). This affects the dependent claims 2-13, 22, 24, 26 and 34-42.

Claims 22 and 24 are vague and indefinite in that the metes and bonds of " a peptide, a peptidomimeic compound" are not defined. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). This affects the dependent claims 2-13, 22, 24, 26 and 34-42. This affects the dependent claim 26.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

February 25, 2002

ALI R. SALIMI
PRIMARY EXAMINER